



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT Application of
Kremminger

Group Art Unit: 1624

Application No. 10/524,397

Examiner: Berch, M. L.

Filed: 11 February 2005

Att. Docket No.: IB/G-32613A

For: CEFDINIR INTERMEDIATE

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3 April 2007

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Notice of Allowance mailed 14 February 2007 is acknowledged with appreciation.

The undersigned recently took over prosecution of the present application and U.S. App'n Ser. Nos. 11/294,116 and 11/295,929, which are believed to relate to Cefdinir technology. The undersigned also is of record in U.S. App'n Ser. Nos. 11/129,425; 10/549,906; and 10/405,648, which are believed to relate to Cefdinir technology.

Upon a review of the file histories of these applications, the undersigned uncovered the documents listed on the attached PTO/SB/08A and B forms, which are believed to be not previously cited in the present application. Copies of these documents are being submitted along with a Request for Continued Prosecution to fully comply with the disclosure requirements.


The prior art relating to cefuroxime, tablet coatings, controlled release mechanisms, and cyclophosphamide coated tablets cited in U.S. App'n Ser. No. 11/295,929 has not been included to avoid overburdening the Examiner.

Please accept this Information Disclosure Statement in compliance with the filed herewith Request for Continued Examination. Please charge any required fee required to consider this Information Disclosure Statement to our Deposit Account No. 50-0687 under Order No. 16502.

This information disclosure statement is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice that effect is earnestly solicited, along with additional time under Rule 97(f), to enable Applicant to comply fully.

Respectfully submitted,
Manelli Denison & Selter, PLLC

By



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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(use as many sheets as necessary)***Complete if Known**

Application Number	10/524,397
Filing Date	02/11/2005
First Named Inventor	Kremminger
Group Art Unit	1624
Examiner Name	Berch, Mark L.
Attorney Docket Number	IB/G-32613A

Sheet 1 of 6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee of Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		2002/0051816		Yamaguchi	02-05-2002	
		2003/0204082	A1	Manca et al.	10-2003	
		2004/0242556	A1	Dandala	12-2004	
		2005/0080255	A1	Kumar et al.	04-2005	
		2005/0113355	A1	Duerst et al.	05-2005	
		2005/0137182	A1	Dandala et al.	06-2005	
		2005/0209211	A1	Law et al.	09-2005	
		2005/0209451	A1	Manca et al.	09-2005	
		2005/0215781	A1	Chandrasekaran et al.	09-2005	
		2005/0245738	A1	Singh	11-03-2005	
		20050059818	A1	Duerst	03-2005	
		20050059819	A1	Duerst	03-2005	
		20050131079		Pujara	16-06-2005	
		2006/0025399	A1	Law et al.	02-2006	
		2006/0029674	A1	Sever et al.	02-2006	
		2006/0040915	A1	Kumar et al.	02-2006	
		2006/0069079	A1	Sever et al.	03-2006	
		2006/0074236	A1	Pozzi et al.	04-2006	

Examiner
SignatureDate
Considered

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3) ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		Number	Kind Code ² (if known)			
		2006/0094703	A1	Deshpande et al.	05-2006	
		2006/0111566	A1	Pozzi et al.	05-2006	
		2006/0122165	A1	Daemon et al.	06-2006	
		2006/0135500		Ohnishi et al.	06-2006	
		2006/0135761		Datta	06-2006	
		2006/0142261		Law et al.	06-2006	
		2006/0142563		Law et al.	06-2006	
		2006/0149056		Singh et al.	07-2006	
		2006/0211676		Law et al.	09-2006	
		2006/0287289		Law	12-2006	
		2007/0021402		Onishi	01-2007	
		4,559,334	A	Takaya et al.	12-1985	
		4,585,860		Takaya et al.	04-29-1986	
		4,935,507		Takaya et al.	06-19-1990	
		5,869,648		Ludescher et al.	2-9-1999	
		6,350,869	B1	Sturm et al.	02-2002	
		6,388,070		Desphande	05-2002	
		7,105,659		Dandeka et al.	09-2006	
		7,157,576		Lee	01-2007	
		7,173,126		Pozzi	02-2007	

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		AT	570/97		Sturm	04-04-1997		
		CA	1,340,604			6-22-1999		
		EP	0304019		Fujisawa Pharmaceutical	5-31-1995		
		EP	1273587	A1	Kameyama et al.	01-2003		
		EP	1609793	A1	Imai et al.	12-2005		
		GB	1038529			8-10-1966		
		JP	59-184186			10-19-1984		
		WO	97/24358		Hanmi Pharmaceuticals	7-10-1997		
		WO	97/07121		Biochemie Gesellschaft	2-27-1997		
		WO	98/06723		Biochemie Gesellschaft	2-19-1998		
		WO	2005/090360	A1	Orchid Chemicals	09-29-2005		
		WO	2006/059753	A1	Ohnishi	06-08-2006		
		WO	2004/046154	A1	Orchid Chem.	06-03-2004		
		WO	2004/016623	A1	Kremminger	02-2004		
		WO	2006/010978	A1	Mukarram	02-02-2006		
		WO	01/079211	A1	Kameyama et al.	01-2001		
		WO	02/098884	A1	Lee et al.	12-2002		
		WO	03/050124	A1	Kumar et al.	06-2003		
		WO	03/091261	A1	Kumar et al.	11-2003		

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		WO	99/55710	A1	Van <i>et al.</i>	11-1999		
		WO	2004/056835	A1	Pozzi <i>et al.</i>	07-2004		
		WO	2004/085443	A1	Imai <i>et al.</i>	10-2004		
		WO	2004/104010	A1	Kumar <i>et al.</i>	12-2004		
		WO	2006/006040	A1	Andrew, <i>et al.</i>	01-2006		
		WO	2006/018807	A1	Aryan <i>et al.</i>	02-2006		
		WO	2006/035291	A1	Kumar <i>et al.</i>	04-2006		
		WO	2006/053625	A1	Pozzi <i>et al.</i>			
		WO	2006/117794		Parthasaradhi	11-2006		
		WO	2006/134607		Murali	12-2006		

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Sheet	5	of	6	Attorney Docket Number	IB/G-32613A

OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Maritza Gonzalez, II Farmaco, Volume 58, Issue 6, June 2003, Pages 409-418	
		Lin, et. al., "The Synthesis of Cefdinir," Henschel Hauzue 9(5) pp. 383-385 (2001) and translation.	
		Translation of JP 02000790 A2 (Attached to Document)	
		Translation of WO 2046175 A1 (Attached to Document)	
		Translation of WO 1079211 A1 (Attached to Document)	
		Sakane, Yakugaku Zasshi 113(9) 605-26 1993 and partial translation	
		The Merck Index, (2001), pages 23-24.	
		Translation of JP 59184186 (Attached to Document)	

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		Cabri, et. al., "Cefdinir: A Comparative Study of Anhydrous vs. Monohydrate Form Microstructure and Tableting Behaviour," European Journal of Pharmaceutics and Biopharmaceutics, Volume 64, Issue 2, pp. 212-221 (Oct. 2006).	
		Cabri, et. al., "Polymorphisms and Patent, Market, and Legal Battles: Cefdinir Case Study," American Chemical Society, published on the internet 20 December 2006 by Organic Process Research & Development.	
		J.K. Guillory: "Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Solids, 1999, edited by Harry G. Brittain, Marcel Dekker Inc.	
		Y. Inamoto, Toshiyaki Kiamura and Takao Tayaka, J. Antibiotics Vol XLI, No 6, 829, (1988)	

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